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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,742	07/19/2006	Brett Finlay	27112-14589	2851

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,742	FINLAY ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-58,71-73 and 86-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *53-58,71-73 and 86-94* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendix A and B*.

DETAILED ACTION

Claims 1-52, 59-70 and 74-85 are cancelled. Claims 53-58, 71-73 and 86-94 are pending.

Applicants reply to the restriction requirement mailed 3/30/09 is acknowledged.

Applicants elected Group VI claims 53-58 and 71-73 drawn to a method of eliciting an immune response against an A/E pathogen, reducing colonization or shedding of an A/E pathogen in an animal comprising administering to the animal an effect amount of the composition of any one of claims 1-7 and elected the species NleA as embodied in SEQ ID NO: 1-3 and 22-24.

Upon further consideration, further restriction is required as set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 53-58, 71-73 and 86-94, drawn to a method of eliciting an immune response against an A/E pathogen, reducing colonization or shedding of an A/E pathogen in an animal comprising administering to the animal an effect amount of the composition comprising a polypeptide which comprises an amino acid sequence substantially identical to the sequence of

SEQ ID NO: 22-24 or fragment or variant thereof or a cell culture supernatant which comprises a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22-24 or fragment or variant thereof.

Group II, claim(s) 53-58, 71-73 and 86-94, drawn to a method of eliciting an immune response against an A/E pathogen, reducing colonization or shedding of an A/E pathogen in an animal comprising administering to the animal an effect amount of the composition comprising a nucleic acid molecule which comprises a nucleotide sequence substantially identical to the sequence of SEQ ID NO: 1-3 or fragment or variant thereof or a nucleic acid molecule encoding a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22-24 or fragment or variant thereof.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature of Group I is anticipated by the art as follows: Hideo et al (JP20023550742A2, cited in IDS) teaches a composition comprising a polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22 or a variant therof or SEQ ID NO: 24 and the nucleic acid molecule encoding said polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22 or a variant thereof or SEQ ID NO: 24 for treating *E. coli* infection. Also see sequence alignment attached as Appendix A and B. Hideo et al teaches a method of treating an

infection with *E. coli* O157:H7, an A/E pathogen with said polypeptide or nucleic acid encoding said polypeptide. See English abstract cited in IDS. Thus, Group I lacks unity with Group II.

Species Election

This application contains claims directed to more than one species of the generic invention.

Group I

Species of the invention drawn to administering :

a) SEQ ID NO: 22 or fragment or variant thereof

b) SEQ ID NO: 23 or fragment or variant thereof

c) SEQ ID NO: 24 or fragment or variant thereof

Group II

Species of the invention drawn to administering :

a) SEQ ID NO: 1 or fragment or variant thereof and nucleic acid molecule encoding SEQ ID NO: 22 or fragment or variant thereof

b) SEQ ID NO: 2 or fragment or variant thereof and nucleic acid molecule encoding SEQ ID NO: 23 or fragment or variant thereof

c) SEQ ID NO: 3 or fragment or variant thereof and nucleic acid molecule encoding SEQ ID NO: 24 or fragment or variant thereof

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Hideo et al (JP20023550742A2, cited in IDS) teaches a composition comprising a polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22 (Appendix A) OR SEQ ID NO: 24 (Appendix B) and the nucleic acid molecule encoding said polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NO: 22 or 24 wherein the polypeptide or nucleic acid is used in a method for treating *E. coli* O157:H7, an A/E pathogen infection. See English abstract of Hideo et al cited in IDS.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645